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EXAMINER	
LU, FRANK WEI MIN	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/886,779	SABANAYAGAM ET AL.	
	Examiner	Art Unit	
	FRANK W. LU	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 7/7/2009.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 11,23-29,34,35 and 39-56 is/are pending in the application.

4a) Of the above claim(s) 53 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 11,23-29,34,35,39-52 and 54-56 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 8/1/2003 is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of species (2) (the first oligonucleotides are different, see claim 53) in the reply filed on April 6,2009 is acknowledged. The traversal is on the ground(s) that "[A]pplicants respectfully submit that these two species have been under prosecution since at least 2003. Specifically, claim 11 has been directed to arrays with identical attaching oligos (compare to claim 52) and 23 has been directed to arrays with different attaching oligos (compare to claim 53). Thus, the Examiner has been searching these two types of arrays for about 6 years without raising the need for restriction".

The above arguments have been fully considered and have not been found persuasive toward the withdrawal of election of the species nor persuasive toward the relaxation of same such that species (1) and (2) will be examined together. Although claim 11 indicates that "each of the plurality of immobilized oligonucleotides also has a same generic oligonucleotide sequence that attaches the plurality of immobilized oligonucleotides to the x and y coordinates of a solid surface", since claim 11 also indicates that each of the plurality of immobilized oligonucleotides comprise two or more copies of an unique sequence of interest extending in the array' s z dimension, each of the plurality of immobilized oligonucleotides in claim 11 is different. Therefore, applicant's argument "claim 11 has been directed to arrays with identical attaching oligos (compare to claim 52)" is incorrect and the examiner has not been searching species (2) for above 6 years as argued by applicant. The requirement is still deemed proper and is therefore made FINAL. Claims 11, 23-29, 34, 35, 39-51, and 53-56 will be examined.

Claim Objections

2. Claim 11 is objected to because of the following informality: "an unique" in the preamble should be "a unique".

3. Claim 23 is objected to because of the following informality: "a sequence of interest" in the preamble should be "a unique sequence of interest" in view of claims 34 and 35.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11, 24-29, 34, and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 11 is rejected as vague and indefinite in view of the phrase "each of the plurality of immobilized oligonucleotides also has a same generic oligonucleotide sequence that attaches the plurality of immobilized oligonucleotides to the x and y coordinates of a solid surface" in the preamble. From the phrase, the first part of the phrase indicates that each of the plurality of immobilized oligonucleotides contains a same generic oligonucleotide while the second part of the phrase appears to indicate that a same generic oligonucleotide is not a part of a same generic oligonucleotide, the first part of the phrase and the second part of the phrase do not correspond each other. Please clarify.

7. Claim 27 or 28 or 29 recites the limitation "the second, identical nucleic acid sequence" in the claim. There is insufficient antecedent basis for this limitation in the claim because there is no "second, identical nucleic acid sequence" in claim 23. Please clarify.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 11, 23, 34, 35, and 39-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith *et al.,* (US Patent No. 5,753,439, filed on May 19, 1995).

Note that this rejection was made in view of the ambiguity of claim 11 (see above rejection under 35 U.S.C 112, second paragraph).

Smith *et al.,* teach arrays of probes. Each probe in the array comprises a constant 5'-region, a constant 3'-region and a variable internal region wherein the variable region comprised one or more repeat sequences. The repeat sequences comprise heterologous or homologous sequences which are variable in length or base sequences. Sequences contain purine or pyrimidine bases or neutral bases such as inosine. Either the nucleic acids or the probes of the array are labeled with a detectable label or fixed to a solid support. Probes are single-stranded or partly single-stranded and partly double-stranded. Arrays comprise between about 10 to about

10,000 different probes (see column 9, lines 18-34). In certain situation, the repeat sequences are about 2 to about 2000 (see column 15, claims 1-3).

Regarding claim 11, since z dimension is relative, the direction which oligonucleotides are attached to an array is considered as z axis. Thus, Smith *et al.,* teach an ordered array of a plurality of immobilized oligonucleotides in the ordered array' s x and y coordinates (ie., the array of probes) wherein each of the plurality of immobilized oligonucleotides comprise two or more copies of a unique sequence of interest (ie., each has 2 to 2000 different repeat sequences, see column 15, claims 1-3) extending in the array' s z dimension , and wherein each of the plurality of immobilized oligonucleotides also has a same generic oligonucleotide sequence (ie., the constant 5'-region, see column 9, lines 18-34) that attaches the plurality of immobilized oligonucleotides to the x and y coordinates of a solid surface and wherein each of the plurality of immobilized oligonucleotides has between the two or more copies of the unique sequence of interest at least one nucleic acid region that is complementary to at least a portion of the same generic oligonucleotide sequence. Although Smith *et al.,* do not teach the method recited in claim 11, since claim 11 is a product-by-process claim, it is well established that even though product-by process claim is limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Regarding claim 23, since z dimension is relative, the direction which oligonucleotides are attached to an array is considered as z axis. Thus, Smith *et al.,* teach an ordered array with a

plurality of immobilized oligonucleotides (ie., the array of probes) attached to the ordered array's x and y coordinates the immobilized oligonucleotides comprising two or more copies of a sequence of interest (ie., each has 2 to 2000 different repeat sequences, see column 15, claims 1-3) extending in the array' s z dimension, wherein each immobilized oligonucleotide has a different sequence attached to the array' s x and y coordinates, and wherein each of the different sequences (ie., each has different 5' region, see 5' regions of T1 and T2 in columns 9 and 10) attached to the array' s x and y coordinates is complementary to the sequence of interest, and wherein two or more copies of the different sequence of interest are repeated along the z dimension of the array. Although Smith *et al.,* do not teach the method recited in claim 23, since claim 23 is a product-by-process claim, it is well established that even though product-by process claim is limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Regarding claims 34 and 35, since at least two copies of a template nucleic acid or a fragment thereof corresponding to the unique sequence of interest in the claims is not structural limitations of claims 11 and 23, claims 34 and 35 are anticipated by Smith *et al.*.

Regarding claims 39-45, Smith *et al.,* teach an ordered array of immobilized nucleic acid sequences (ie., the array of probes) attached to a solid support comprising a plurality of identical oligonucleotide sequences (ie., the constant 5'-region, see column 9, lines 18-34) attached to the solid support wherein each of the identical oligonucleotide sequences is followed by at least two

copies of a sequence (ie., each has 2 to 2000 different repeat sequences, see column 15, claims 1-3) that is complementary to a sequence of interest and wherein the sequence that is complementary to the sequence of interest is different for each of the immobilized nucleic acid sequence (ie., the repeat sequences comprise heterologous or homologous sequences which are variable in length or base sequences, see column 9, lines 18-34), and wherein each of the at least two copies of a sequence that is complementary to a sequence of interest is separated by a nucleic acid region (ie., a repeat sequence between other two repeat sequences) that is at least partially complementary to the sequence of the plurality of identical oligonucleotide sequences as recited in claim 39 wherein each sequence of interest corresponds to a unique portion of a target sequence as recited in claim 40, the unique portion of the target sequence is more than 20 nucleotides long (ie., 25 nucleotides in length, see claims 1 and 12-14, see columns 15 and 16) as recited in claim 41, the nucleic acid region (ie., a repeat sequence between other two repeat sequences) that is at least partially complementary to the sequence of the plurality of identical oligonucleotide sequences is longer than 6 nucleotides (ie., 7-25 nucleotides in length) as recited in claim 42, each immobilized nucleic acid sequence comprises three or more copies (ie., 3-2000 repeat sequences, see column 15, claims 1-3) of said sequence that is complementary to a sequence of interest as recited in claim 43, each immobilized nucleic acid sequence comprises ten or more copies (ie., 10-2000 repeat sequences, see column 15, claims 1-3) of said sequence that is complementary to a sequence of interest as recited in claim 44, each immobilized nucleic acid sequence comprises more than fifty copies (ie., 51-2000 repeat sequences, see column 15, claims 1-3) of said sequence that is complementary to a sequence of interest as recited in claim 45.

Regarding claims 46-49, Smith *et al.,* teach an ordered array of immobilized nucleic acid sequences (ie., the array of probes) attached to a solid surface comprising a plurality of nucleic acid sequences attached to the solid surface, wherein each of the attached nucleic acid sequence is different (ie., each has different 5' region, see 5' regions of T1 and T2 in columns 9 and 10) and comprises at least two copies (ie., 2 to 2000 repeat sequences) of a sequence that is complementary to a sequence of interest, wherein the sequence that is complementary to a sequence of interest is more than 13 nucleotides long (ie., 14-25 nucleotides in length, see claims 1 and claims 12-14) as recited in claim 46 wherein each immobilized nucleic acid sequence comprises three or more copies (ie., 3-2000 repeat sequences, see column 15, claims 1-3) of said sequence that is complementary to a sequence of interest as recited in claim 47, each immobilized nucleic acid sequence comprises ten or more copies (ie., 10-2000 repeat sequences, see column 15, claims 1-3) of said sequence that is complementary to a sequence of interest as recited in claim 48, each immobilized nucleic acid sequence comprises more than fifty copies (ie., 51-2000 repeat sequences, see column 15, claims 1-3) of said sequence that is complementary to a sequence of interest as recited in claim 49.

Regarding claims 50-52 and 54-56, Smith *et al.,* teach an ordered array of immobilized nucleic acids (ie., the array of probes) comprising of a solid surface, a plurality of first oligonucleotides (ie., the constant 5' region) attached to said solid surface and a second nucleic acid (ie., the variable region and constant 3' region) at least partially hybridized to each of said first oligonucleotides, wherein the second nucleic acid comprises a region that is at least partially complementary to the first oligonucleotide and two or more copies (ie., 2-2000 repeat sequences) of a sequence of interest as recited in claim 50 (see column 9, lines 18-34, claims 1-3

in column 15 and claims 48-55 in column 18) wherein the two or more copies of the sequence of interest are separated by a nucleic acid sequence forming a separating region between each sequence of interest as recited in claim 51, the plurality of first oligonucleotides are identical (ie., the constant 5' region, see claims 48-55 in column 18) as recited in claim 52, each second nucleic acid comprises three or more copies (ie., 3-2000 repeat sequences, see column 15, claims 1-3) of said sequence of interest as recited in claim 54, each second nucleic acid comprises ten or more copies (ie., 10-2000 repeat sequences, see column 15, claims 1-3) of said sequence of interest as recited in claim 55 and each second nucleic acid comprises more than fifty copies (ie., 51-2000 repeat sequences, see column 15, claims 1-3) of said sequence of interest as recited in claim 56.

Therefore, Smith *et al.,* teach all limitations recited in claims 11, 23, 39-52 and 54-56.

Response to Arguments

10. Applicant's arguments with respect to claims 11 and 23-38 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. No claim is allowed.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen, can be reached on (571)272-0731.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Frank W Lu /
Primary Examiner, Art Unit 1634
November 16, 2009